

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS US LLC, ASTELLAS
PHARMA US, INC. and GILEAD
SCIENCES, INC.,

Plaintiffs,

v.

APOTEX INC.,

Defendant.

C.A. No. 18-1675 (CFC)
(Consolidated)



REDACTED

[PROPOSED] JOINT PRETRIAL ORDER

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LIST OF EXHIBITS IN JOINT PRETRIAL ORDER

STATEMENT OF FACTS WHICH ARE ADMITTED AND REQUIRE NO PROOF

Joint	--	Exhibit 1
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ISSUES OF FACT THAT REMAIN TO BE LITIGATED

Plaintiffs	--	Exhibit 2
Defendants	--	Exhibit 3

ISSUES OF LAW THAT REMAIN TO BE LITIGATED

Plaintiff	--	Exhibit 4
Defendant	--	Exhibit 5

WITNESSES

Plaintiffs	--	Exhibit 6
Defendants	--	Exhibit 7

DEPOSITION DESIGNATIONS

Plaintiffs	--	Exhibit 8
Defendants	--	Exhibit 9

EXHIBITS

Plaintiffs and Defendants	--	Exhibit 10
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BRIEF STATEMENTS OF INTENDED PROOFS

Plaintiffs	--	Exhibit 11
Defendants	--	Exhibit 12

MOTIONS *IN LIMINE*

DRL/IMS/Hospira/Apotex MIL		Exhibit 13
Sun MIL		Exhibit 14

COVID-19 SAFETY PROTOCOL

Joint	--	Exhibit 15
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This matter comes before the Court at a final pretrial conference held on January 21, 2022 pursuant to Rule 16 of the Federal Rules of Civil Procedure.

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I. NATURE OF THE CASE

1. This is a consolidated patent infringement action brought by Plaintiffs against Defendants for infringement of U.S. Patent Nos. 8,106,183 (the “’183 patent”); RE 47,301 (the “’301 patent”); and 8,524,883 (the “’883 patent”) (collectively, the “Patents-in-Suit”) under 35 U.S.C. §§ 271(a), (b), (e)(2), and/or (g).

2. Plaintiffs contend that each of the patents-in-suit covers Plaintiffs’ LEXISCAN® (regadenoson) product, which is approved by the U.S. Food and Drug Administration (“FDA”) for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress. The ’183 and ’301 patent are listed in the FDA Approved Drug Products and Therapeutic Equivalents publication (“the Orange Book”) for the New Drug Application relating to LEXISCAN®.

3. Plaintiffs contend that their infringement claims arise out of the filing by each of Defendants Apotex, IMS, Hospira, DRL, and Sun with FDA of an Abbreviated New Drug Application (“ANDA”), seeking approval for generic versions of Plaintiffs’ LEXISCAN® (regadenoson) product before the expiration of the patents-in-suit. Plaintiffs contend that their infringement claims of the ’883 patent arise under the Declaratory Judgment Act. Defendants do not contest subject matter jurisdiction.

4. The claims asserted against Defendants (“asserted claims”) are set forth below:

Defendant	’183 Patent	’883 Patent	’301 Patent
DRL	1, 9	1-3	6, 8, 17
Hospira	1, 9	1-3	6, 8, 17
IMS	1, 9	1-3	6, 8, 17
Apotex	6	1-3	6, 8, 17
Sun	6-7	1-3	6, 8, 17

5. The trial is currently scheduled to begin on January 27, 2022.

II. JURISDICTION

6. This action arises under the patent laws of the United States, Title 35, United States Code. Jurisdiction over the parties’ claims and counterclaims lies under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 and is not disputed.

7. Venue over this case is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) and is not disputed.

III. FACTS

A. Uncontested Facts

8. A joint statement of uncontested facts is set forth in **Exhibit 1**. These proposed uncontested facts require no proof at trial and will become part of the

evidentiary record in this case. Any party, with prior notice to all other parties, may read any or all of the uncontested facts to the Court, and will be charged for the time used to do so.¹ However, a party need not read these facts into the record for them to be considered by the Court in reaching its ultimate judgment as they are considered part of the record as of the issuance of this Order.

B. Contested Facts

9. Plaintiffs' statement of issues of fact that remain to be litigated and expected proof is attached as **Exhibit 1**.

10. Defendants' statement of issues of fact that remain to be litigated and expected proof is attached as **Exhibit 2**.

IV. ISSUES OF LAW

11. Plaintiffs' statement of issues of law that remain to be litigated is attached as **Exhibit 3**.

12. Defendants' statement of issues of law that remain to be litigated is attached as **Exhibit 4**.

V. WITNESSES TO BE CALLED IN PERSON OR BY DEPOSITION

A. List of Witnesses Plaintiffs Expect to Call

13. Plaintiffs' list of the names of the fact and expert witnesses Plaintiffs currently intend to call live or by deposition at trial is attached as **Exhibit 6**.

¹ As used herein, the term "party" is used to refer to either Plaintiffs or Defendants, collectively, except as otherwise indicated.

Plaintiffs further identify any witness listed on Defendants' witness disclosure and reserve the right to call any witness, whether or not identified, in rebuttal or for purposes of impeachment. Plaintiffs currently expect that the witnesses that Plaintiffs intend to call live will testify in-person at trial, but reserve the right to present witnesses via videoconference at trial due to travel restrictions and health concerns related to the COVID-19 pandemic.

B. List of Witnesses Defendants Expects to Call

14. Defendants' list of the names of the fact and expert witnesses Defendants currently intend to call live (either in person or remotely) or by deposition at trial is attached as **Exhibit 7**. Defendants further identify any witness listed on Plaintiffs' witness disclosure and reserve the right to call any witness, whether or not identified, in rebuttal or for purposes of impeachment. As noted in Exhibit 7, Defendants currently expect that four of the witnesses that Defendants intend to call live will testify via videoconference at trial due to travel restrictions and health concerns related to the COVID-19 pandemic. *See* 5-26-2021 Hearing Tr. at 14:7-13, 20:24-23:9.

C. List of Witnesses Third Parties Expect to Call

15. With the exception of deposition testimony designated by the parties and witnesses listed in Exhibits 6 and 7, the parties are not aware of any other third parties who intend to participate in this action.

D. Agreed Upon Procedures

16. Any witness not listed in **Exhibits 6 and 7** will be precluded from testifying, whether live (via videoconference or in-person) or by deposition, absent good cause shown.

17. With the exception of expert witnesses, each witness will testify only once, either live or by deposition.

18. By **6:00 p.m.** on January 21, 2022, the parties will exchange in good faith final witness lists. For planning purposes, the parties will identify which of those witnesses they expect to testify live, which they expect to testify by videoconference, and which they expect to testify by deposition at that time.

19. The listing of a witness on a party's witness list does not require that the party call that witness to testify, either live or by deposition.

20. Each party will provide the other party with a list, in order of presentation, of witnesses it intends to call live on direct examination by **7:00 p.m.** two nights before those witnesses are intended to testify in Court. (For example, if a party intends to call a witness on Wednesday, that party shall disclose that witness's name to the opposing party no later than **7:00 p.m.** on Monday.) This list must also include those witnesses who are to be called by designation (whose designations will have been previously disclosed pursuant to the procedures described below), and shall identify the manner in which the witnesses will appear

(i.e. live, by videoconference, or by designation). Each party shall exchange the order of witnesses who appear by deposition in good faith, subject to changes by agreement by the parties or for good cause shown.

21. The other parties shall identify any objections to such witness(es) by **7:00 p.m.** the following day, and the parties shall meet and confer to resolve any objections by **10:00 p.m.** that same evening. If good faith efforts to resolve the objections are unsuccessful, the party objecting to the witness shall bring its objections to the Court's attention at the beginning of the following day. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

22. With the exception of expert witnesses and a corporate representative for each party, the parties agree that witnesses should be prevented from hearing the testimony of other witnesses pursuant to Federal Rules of Evidence 615. Counsel for the parties shall notify one another by e-mail of their corporate representative no less than three days before the first day of trial—i.e., by January 24, 2022.

E. Testimony by Designation

23. A chart of Plaintiffs' deposition designations, Defendants' objections to Plaintiffs' deposition designations, Defendants' counter-designations, and

Plaintiffs' objections to Defendants' counter-designations are set forth in **Exhibit 8** hereto. Plaintiffs' deposition designations are subject to revision.

24. A chart of Defendants' deposition designations, Plaintiffs' objections to Defendants' deposition designations, Plaintiffs' counter-designations, and Defendants' objections to Plaintiffs' counter-designations are set forth in **Exhibit 9** hereto. Defendants' deposition designations are subject to revision.

25. Unless otherwise agreed between the parties, the party offering deposition testimony (other than for the purpose of impeachment) shall identify the deposition testimony to be offered from previously-exchanged designations by **7:00 p.m.** at least two calendar days prior to the testimony being offered into the record. The party receiving the designations shall inform the opposing party of any objections and counter-designations by **7:00 p.m.** at least one calendar day prior to the testimony being offered into the record. Any objections to counter-designations shall be provided by **9:00 p.m.** that same day. The parties shall meet-and-confer by **10:00 p.m.** to resolve any objections that same day. If good faith efforts to resolve the objections are unsuccessful, the party objecting to the designations shall bring its objections to the Court's attention at the beginning of the following day.

26. The party who initially proposes the use of the deposition testimony will provide the Court with an accounting of the time for each party's designations

based on the parties' proportional share of lines of testimony for read-in testimony and by actual time for video testimony so that the Court may accurately charge time to the designating parties.

27. All irrelevant and redundant material, including colloquy between counsel and objections, or pauses between questions, will be eliminated when the deposition is read or viewed at trial.

28. When deposition designation excerpts are introduced, all admissible deposition designation, and counter-designation excerpts, whether offered by videotape or by transcript, will be introduced simultaneously in the sequence in which the testimony was originally given. The specific portions of the deposition shall be read or played in page order. If an exhibit is referenced in a deposition designation, the exhibit is admitted into evidence if it is included on the offering party's trial exhibit list and is not otherwise objected to.

29. When the witness is called to testify by deposition at trial, the party calling the witness shall provide the Court with two copies of the transcript of the designations and counter-designations.

F. Impeachment with Prior Inconsistent Testimony

30. The Court may allow objections to efforts to impeach a witness with prior testimony, including objections based on lack of completeness and/or lack of consistency. The above procedures regarding deposition designations do not apply

to portions of deposition transcripts and/or video used for impeachment of a witness. Any deposition testimony may be used at trial for the purpose of impeachment, regardless of whether a party specifically identified that testimony on its list of deposition designations, if the testimony is otherwise competent for such purpose.

G. Objections to Expert Testimony

31. The parties agree that the Court should rule at trial on objections to expert testimony as beyond the scope of prior expert disclosures, taking time from the parties' trial presentation to argue and decide such objections. Thus, the time taken by the Court to hear and consider the objection shall be charged to the party that does not prevail. For example, if a party raises an objection that expert testimony is beyond the scope and the objection is overruled, the time to consider the objection will be charged to the objecting party.

VI. EXHIBITS

A. Exhibits

32. **Exhibit 10** contains a listing of the parties' exhibits, which includes:

- (a) Plaintiffs' exhibits, identified by the prefix PTX; and
- (b) Defendants' joint exhibits, identified by the prefix DTX.
- (c) Defendant Apotex's exhibits, identified by the prefix ATX.
- (d) Defendant DRL's exhibits, identified by the prefix RTX.

(e) Defendant Hospira's exhibits, identified by the prefix HTX.

(f) Defendant IMS' exhibits, identified by the prefix ITX.

(g) Defendant Sun's exhibits, identified by the prefix STX.

33. **Exhibit 10** contains the maximum universe of exhibits that may be used by any party's case-in-chief, as well as all objections to the admission of such objections, neither of which shall be supplemented without approval of all parties or leave of the Court, on good cause shown. A party may offer any exhibit appearing on any party's exhibit list. Exhibits not listed will not be admitted unless good cause is shown.

34. Absent an agreement of the parties or a directive from the Court adopting an alternative procedure, the following rules govern the admission of exhibits:

35. Any party may use an exhibit that is listed on the other party's exhibit list, to the same effect as though it were listed on its own exhibit list, subject to all evidentiary objections. Any exhibit, once admitted, may be used equally by each party, subject to any limitations as to its admission.

36. Exhibits to be used solely for impeachment need not be included on the trial exhibit lists or disclosed in advance of being used at trial.

37. Any exhibit identified on a party's exhibit list and not objected to is deemed to be admissible and may be entered into evidence by the party, as long as

a proper foundation is laid and a witness testifies about the exhibit, except that nothing herein shall be construed as a stipulation or admission that the document is entitled to any weight in deciding the merits of this case.

38. The parties will work out stipulations that certain documents, including the Patents-in-Suit and relevant NDA, ANDAs, DMFs, and IND are authentic and/or admissible.

39. Absent an agreement by the parties or an Order of the Court, no exhibit will be admitted unless offered into evidence through a witness, testifying live or by deposition, who must at least be shown and give testimony about the exhibit. Prior to the completion of a live witness' testimony, any party that has used an exhibit with the witness and wishes that exhibit to be admitted into evidence must formally move the exhibit into evidence.

40. [Contested] Plaintiffs' Proposal: Unless otherwise agreed to by the parties during the trial, the parties will each provide to each other's counsel of record via e-mail a written list of exhibits, by exhibit number, for each witness that it intends to call in Court by **7:00 p.m.** two calendar days before the day the witness will testify. Objections to any of the disclosed exhibits shall be made by no later than **7:00 p.m.** the following day, and the parties will meet and confer regarding any objections by **9:00 p.m.** that same evening. If good faith efforts to resolve the objections fail, the party objecting to the exhibits shall bring its

objections to the Court's attention prior to the witness being called to the stand. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

41. [Contested] Defendants' Proposal: Unless otherwise agreed to by the parties during the trial, the parties will each provide to each other's counsel of record via e-mail a written list of exhibits, by exhibit number, for each witness that it intends to call in Court by **7:00 p.m.** one calendar day before the day the witness will testify. Objections to any of the disclosed exhibits shall be made by no later than **9:00 p.m.** the same day, and the parties will meet and confer regarding any objections by **10:00 p.m.** that same evening. If good faith efforts to resolve the objections fail, the party objecting to the exhibits shall bring its objections to the Court's attention prior to the witness being called to the stand. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of an exhibit or waiver of objection to the exhibit.

42. The parties will exchange a list of exhibits they plan to use in opening statements by **12:00 p.m.** the day before the start of trial. The parties will provide any objections to such exhibits no later than **3:00 p.m.** the same day. The parties agree to meet and confer to the extent objections remain pending no later than **5:00**

p.m. on the day before the start of trial to attempt to resolve any such objections so that exhibits may be used during opening statements or objections can be resolved by the Court.

43. Legible photocopies of United States patents and the content of PTO file histories may be offered and received in evidence in lieu of certified copies thereof. The parties reserve their rights to object to any photocopy that is not identical to the certified copy.

44. Legible photocopies of printed publications (with agreed upon English translations thereof) may be offered and received in evidence in lieu of originals thereof. The parties reserve their rights to object to any photocopy that is not identical to the original.

45. The parties stipulate that a duplicate of any document or photograph may be marked for identification, and, if otherwise admissible, offered and received into evidence with the same force and effect as the original, subject to any and all objections as could be made to the original, and on condition that the original of any such duplicate, if within the custody or control of a party, be available for inspection at the trial upon reasonable notice.

46. If closing argument is allowed, the parties agree that any exhibit that has been admitted into evidence during the course of trial can be used in closing

argument and that the parties need not disclose the intent to use any admitted exhibit prior to closing arguments.

47. The exhibit lists indicate whether each trial exhibit has previously been marked as a deposition exhibit. To remove duplicates and improve legibility of the exhibits used at trial, the parties agree that the trial exhibit shall be treated as identical to the indicated deposition exhibit regardless of whether it bears a deposition exhibit sticker.

48. On or before the first day of trial, each party will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list corresponding to their respective final exhibit lists.

B. Demonstratives

49. The parties agree that the demonstrative exhibits the parties intend to use at trial do not need to be included on their respective lists of trial exhibits. Plaintiffs' demonstratives will be identified with PDX numbers. Defendants' demonstratives will be identified with DDX numbers. Defendant specific demonstratives will be identified as follows:

For Apotex: ADX.

For DRL: RDX.

For Hospira: HDX.

For IMS: IDX.

For Sun: SDX.

50. Demonstratives to be used on direct examination will be exchanged pursuant to the procedures set forth below. These provisions do not apply to demonstratives created during testimony or demonstratives to be used for cross-examination, neither of which need to be provided to the other side in advance of their use. In addition, demonstratives reflecting blow-ups or highlights of exhibits or parts of exhibits or testimony are not required to be provided to the other side in advance of their use.

51. The parties will exchange demonstratives to be used in opening statements by **12:00 p.m.** the day before the start of trial. The parties will provide any objections to such demonstratives no later than **3:00 p.m.** the same day. The parties will confer regarding any such objections no later than **5:00 p.m.** the same day.

52. A party will provide demonstrative exhibits to be used in connection with direct examination by **7:00 p.m.** the night before their intended use, and objections will be provided not later than **9:00 p.m.** the night before their intended use. The parties will then meet and confer in an attempt to resolve any objections to the demonstratives that are expected to be used during direct examinations no later than **10:00 p.m.** that same evening.

53. The party seeking to use a demonstrative will provide to the other side a color representation of the demonstrative to the other side in PDF form.

However, for video or animations, the party seeking to use the demonstrative will provide it to the other side on a DVD, CD, or other electronic means (e.g., file transfer). For irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as an 8.5 x 11 PDF.

54. If good faith efforts to resolve objections to demonstratives fail, the objecting party shall bring its objections to the Court's attention before its intended use. Failure to comply with these procedures, absent an agreement by the parties and approval by the Court, will result in waiver of the use of a demonstrative or waiver of objection to the demonstrative.

VII. BRIEF STATEMENTS OF INTENDED PROOF

55. Plaintiffs' statement of what Plaintiffs intend to prove at trial is attached as **Exhibit 11**.

56. Defendants' statement of what Defendants intend to prove at trial is attached as **Exhibit 12**.

VIII. DAMAGES

57. There currently are no damages claims in the case.

IX. MOTIONS IN LIMINE

58. At this time, Plaintiffs do not intend to file motions *in limine*.

59. Defendants Apotex, DRL, Hospira, and IMS's motion *in limine* and Plaintiffs' opposition are attached as **Exhibit 13**.

60. Sun's motion *in limine* and Plaintiffs' opposition are attached as **Exhibit 14**.

X. COVID-19 SAFETY PROTOCOL

61. The parties' proposed COVID-19 safety protocol is attached as **Exhibit 15**.

XI. DISCOVERY

62. All parties have completed discovery. Supplemental discovery with regard to Defendants DRL, IMS, Hospira, and Apotex closed on December 8, 2021.²

XII. NON-JURY TRIAL

A. Presentation of Evidence and Argument

63. The trial shall proceed based on the customary orders of proof. Plaintiffs shall present their opening statements on all issues, followed by Defendants' opening statement on all issues. Plaintiffs shall present their affirmative case on infringement, followed by Defendants' rebuttal on infringement and affirmative case on invalidity. Plaintiffs shall then present their rebuttal on

² Defendants DRL, IMS, Hospira, and Apotex note that their Motions to Strike (D.I. 824, 830) and their related motion *in limine* remain pending and reserve all rights with respect to their motions and any ruling(s) related to the same.

infringement and invalidity. If the Court allows closing arguments, Plaintiffs shall then present their closing argument on its affirmative case on infringement followed by Defendants' closing argument on all issues, followed by Plaintiffs' rebuttal closing argument on invalidity.

B. Process for Post-Trial Briefing

64. Along with their post-trial briefs, Plaintiffs and Defendants shall provide proposed Findings of Fact and Conclusions of Law, separately stated in numbered paragraphs, constituting a detailed listing of the relevant material facts the party believes it has proven, in a simple narrative form, along with citations to the record. For the Proposed Findings of Fact, for infringement, the Plaintiffs shall have a maximum of 8,000 words for each Defendant and each Defendant, likewise, has 8,000 words to respond to the Plaintiffs; for invalidity each side has 12,500 words, or a number of words chosen after trial based on the Court's preferences and instructions.

65. In their opening post-trial briefs, Plaintiffs shall address infringement (20,000 words for all Defendants) and Defendants shall address validity (20,000 words), or for each party within a number of words chosen after trial based on the Court's preferences and instructions. In addition to Plaintiffs' opening brief on infringement, Plaintiffs shall present evidence and argument regarding injunctive

relief for the '883 patent during post-trial briefing (8,000 words), or within a number of words chosen after trial based on the Court's preferences and instructions.

66. Opening post-trial briefs and proposed findings of fact and conclusions of law and shall be due on February 18, 2022, or on a date chosen after trial based on the Court's preferences and instructions.

67. Responsive briefs shall be due on March 11, 2022, or on a date chosen after trial based on the Court's preferences and instructions. Plaintiffs will address validity (20,000 words), and Defendants will address infringement (20,000 words collectively) and injunction (8,000 words), or for each party within a number of words chosen after trial based on the Court's preferences and instructions.

68. Reply briefs shall be due on March 18, 2022, or on a date chosen after trial based on the Court's preferences and instructions. Plaintiffs will address infringement (6,250 words) and injunction (2,500 words) and Defendants will address validity (6,250 words), or for each party within a number of words chosen after trial based on the Court's preferences and instructions.

XIII. LENGTH OF TRIAL

69. The trial will be timed. Unless otherwise ordered, time will be charged to a party for its opening statement, direct and redirect examinations of witnesses it calls, cross-examination of witnesses called by any other party, closing arguments, its arguments on any motions for judgment as a matter of law, and all

sides' arguments on objections a party raises to another party's exhibits and demonstrative exhibits.

70. The Courtroom Deputy will keep a running total of trial time used by counsel.

71. The parties understand that the trial will start on January 27, 2022 and will continue into the week of January 31. The parties understand that the Court will determine the exact duration of the trial, and the provided time will be split equally between the two sides as determined by the Court.

XIV. AMENDMENTS OF THE PLEADINGS

72. Neither party intends to seek an amendment to the pleadings.

XV. ADDITIONAL MATTERS

A. Handling of Confidential Information at Trial

73. The parties anticipate that the majority of the trial will be open to the public and not sealed unless a party specifically requests that a particularly sensitive portion be sealed. If a party makes such a request, subject to the Court's approval, and for good cause shown, the courtroom shall be cleared of those individuals not qualified under the Protective Order entered in this case to view the Confidential Information of the requesting Party.

B. Miscellaneous Issues

74. Sun's objection to Plaintiffs' substantive revisions the evening before the filing of the Pretrial Order, attempting to introduce facts, theories and

arguments not previously disclosed and outside the scope of expert discovery in Plaintiffs' infringement case with Sun. Plaintiffs disagree with Sun's position regarding Plaintiffs' theories of infringement and disclosure of such theories.

XVI. SETTLEMENT

75. Plaintiffs and each of the Defendants certify that they have engaged in good faith efforts to explore the resolution of the case by settlement, including the exchange of draft agreements as well as discussions. The dates of the last discussions for each defendant are set forth below:

DRL: [REDACTED]

IMS: [REDACTED]

Hospira: [REDACTED]

Sun: [REDACTED]

Apotex: [REDACTED]

IT IS HEREBY ORDERED that this order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

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IT IS SO ORDERED on this ____ day of____, 2022.

The Honorable Colm F. Connolly